

REMARKS/ARGUMENTS

Claims 1-11 are pending in the present application. Claims 1 and 11 have been amended for reasons of clarity and precision of language. For at least the reasons that follow, Applicant submits that claims 1-11, as amended, are in condition for allowance.

Statement of Substance of Interview

Applicant thanks Examiner Spivack for the courteous telephonic interview which took place on May 13, 2009. An Examiner's Interview Summary Record (PTOL-413) was provided to Applicant.

During the interview, the rejection of claim 11 on the ground of non-statutory obviousness-type double patenting over U.S. Patent No. 5,519,014 was discussed. Clarification was suggested to overcome the rejection.

35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph, for the stated reason that the specification does not reasonably provide enablement for methods of “prophylaxis” within the full scope of the claims. Applicants respectfully submit that claims 1-11 satisfy the enablement requirement.

Independent claims 1 and 11 recite a method for the prophylaxis of one condition – non-inflammatory irritable bowel syndrome. Applicant submits the declaration of Dr. Thomas Julius Borody under 37 C.F.R. § 1.132 in support of the position that the present specification enables the prophylaxis of non-inflammatory irritable bowel syndrome. As Dr. Borody explains, a person familiar with the technology involved in the application in early 2004 would understand that non-inflammatory irritable bowel syndrome is an episodic disorder that at times will “settle down” and at other times will “flare-up”. (Borody Dec. ¶ 6.)

Reading the Examples in the specification, the person familiar with the technology would have understood that the patients described there were treated for irritable bowel syndrome but that also the continued administration of the compound was having a **prophylactic effect** on the irritable bowel syndrome. In other words, once the ongoing “flare-up” had settled down, the continued therapy ended up being a prophylaxis that prevented recurrence of the irritable bowel syndrome. (Borody Dec. ¶ 7.) Thus, by simply reading the examples in the patent application, a person familiar with the technology in early 2004 would have understood how to, and would have been able to, achieve a prophylaxis of diarrhoea predominant irritable bowel syndrome. (Borody Dec. ¶ 8.)

Applicant also notes that, contrary to other diseases, the presence of irritable bowel syndrome is determined and characterized by a collection of symptoms **in**

the absence of disease. To support this statement, Applicant attaches as Exhibit A a web page describing the Rome Criteria for irritable bowel syndrome. Significantly, the criteria listed on the web page are a collection of symptoms. Because irritable bowel syndrome (IBS) is characterized in this way, treating the symptoms of IBS *is treatment of IBS* while preventing recurrence of the symptoms of IBS *is prophylaxis of IBS*.

Applicant therefore respectfully submits that claims 1 and 11, as well as the claims that depend therefrom, are enabled by the specification.

Obviousness-Type Double Patenting

Claim 11 stands rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8 and 9 of U.S. Patent No. 5,519,014. Applicant requests reconsideration of this rejection in view of the amendments made to Claim 11. The amendments clarify that both the 4-aminosalicylic acid compound and the 5-aminosalicylic acid compound are modified to include a 4-aminobenzoyl- β -alanine side chain.

35 U.S.C. § 103 (Obviousness)

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilson et al. (WO 2005/030173). Claim 11 stands rejected under 35 U.S.C. §

103(a) as being unpatentable over Wilson in view of Lin et al. (U.S. Patent No. 6,326,364).

Applicant continues to submit that even if Wilson can be properly applied as prior art, it is distinguishable from the presently claimed subject matter. Independent claims 1 and 11 are limited to non-inflammatory intestinal disorders. Wilson contains no specific teaching of the use of balsalazide to treat non-inflammatory bowel diseases.

In any event, Applicant has submitted a declaration under 37 C.F.R. § 1.131 in order to swear behind the Wilson reference. As Mr. Shortis explains in detail in his declaration, he both conceived and reduced subject matter claimed to practice prior to September 25, 2003, which is the purported effective filing date of Wilson. In view of this declaration, Applicant submits that Wilson can no longer be applied as prior art. Applicant respectfully requests withdrawal of the obviousness rejections of claims 1-11, all of which rely on Wilson.

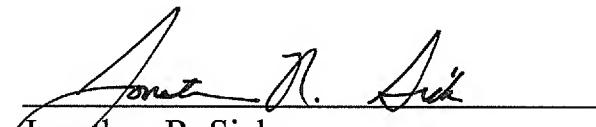
Conclusion

For the foregoing reasons, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims 1-11.

If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited and encouraged to contact the Applicant at the number below.

Please charge any required fees, or credit any overpayment, incurred in connection with this submission to Deposit Account No. 13-0017.

Respectfully submitted,



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Dated: June 24, 2009

About.com Inflammatory Bowel Disease (IBD)

Exhibit A



Internet Explorer cannot display the webpage

Most likely causes:

The Rome Criteria for IBS

This group of criteria can help diagnose IBS.

By Amber J. Tresca, About.com *Created: November 29, 2003*

About.com Health's Disease and Condition content is reviewed by the Medical Review Board

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Irritable Bowel Syndrome (IBS) is largely classified as a condition of exclusion. In other words, IBS is usually diagnosed after all other causes of symptoms such as infection or disease are ruled out. This is costly, time consuming, and very inconvenient for patients as well as physicians. In the late '70s and early '80s researchers began to look more closely at IBS as a serious disorder and not just a psychosomatic problem.

The first attempt at classifying the symptoms of IBS is known as the Manning Criteria. It was later discovered that these criteria are not specific enough and are unreliable for use with men who have IBS. Despite these shortcomings, the Manning Criteria are a very important step in defining symptoms of IBS.

The Manning Criteria are:

1. Onset of pain linked to more frequent bowel movements
2. Looser stools associated with onset of pain
3. Pain relieved by passage of stool
4. Noticeable abdominal bloating
5. Sensation of incomplete evacuation more than 25% of the time
6. Diarrhea with mucous more than 25% of the time

At the 13th International Congress of Gastroenterology in Rome, Italy in 1988 a group of physicians defined criteria to more accurately diagnose IBS. Known as the "Rome Criteria," this set of guidelines that outlines symptoms and applies parameters such as frequency and duration make possible a more accurate diagnosis of IBS.

The Rome criteria are:

1. 3 months of continuous or recurring symptoms of abdominal pain or irritation that
 - May be relieved with a bowel movement,
 - May be coupled with a change in frequency, or
 - May be related to a change in the consistency of stools.
2. Two or more of the following are present at least 25 percent (one quarter) of the time:
 - A change in stool frequency (more than 3 bowel movement per day or fewer than 3 bowel movements per week)
 - Noticeable difference in stool form (hard, loose and watery stools or poorly formed stools)
 - Passage of mucous in stools
 - Bloating or feeling of abdominal distention
 - Altered stool passage (e.g. sensations of incomplete evacuation, straining, or urgency)

Symptoms in the Rome Criteria are not the only indicators of IBS. Extra intestinal symptoms include:

- Nausea
- Fatigue
- Full sensation after even a small meal
- Vomiting

The Rome Criteria were not widely accepted when originally presented, but were better received after their first revision. This second version, created in 1992 and known as Rome II, added a length of time for symptoms to be present and pain as an indicator. The second revision, known as Rome III, is currently underway.

Explore Inflammatory Bowel Disease (IBD)

See More About:

- diagnosing ibs
- rome criteria
- manning criteria

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